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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,298	02/25/2002	Kenneth Jacobs	GI 5358 CIP	7985

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EXAMINER	
KAPUST, RACHEL B	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,298	JACOBS ET AL.	
	Examiner	Art Unit	
	Rachel B. Kapust	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10, 12-14, 16-20, and 34-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,12-14,16-20 and 34-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III (claims 10-12, 14-16, and 24) is acknowledged. The traversal is based on the ground(s) that Group VIII (claims 10, 24, and 17-20) as drawn to a method for treating symptoms associated with arthritis should be rejoined with Group III. Applicant's arguments have been fully considered and have been found to be persuasive. Claims 10, 24, and 17-20 will be examined with the claims of Group III such that the claims are drawn to a method of treating autoimmune disorders.

The restriction requirement is still deemed proper and is therefore made FINAL. Claims 1-9, 11, 15, and 21-33 have been cancelled by Applicant. Claims 10, 12-14, 16-20, and 34-45 are under consideration.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (*i.e.*, continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Also, the current status of all nonprovisional parent applications referenced should be included. It appears that Applicant intends to claim priority from Application No. 09/561,811 filed April 28, 2000 and that the current application is a continuation-in-part of the '811 application.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see p. 13). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The use of the trademarks TOYOPEARL™ (p. 21), SEPHAROSE™ (p. 21), CREMOPHOR EL™ (p. 29), and GENECHIP™ (p. 63) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 12-14, 16-20, and 34-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoutier *et al.* (2000, *PNAS* 97(18): 10144-10149, submitted by Applicants in October 2002 IDS) and U.S. Patent 6,551,799 in view of Llorente *et al.* (2000, *Arthritis & Rheumatism* 43(8): 1790-1800). As stated above, it appears that the current application is a continuation-in-part of U.S. Application 09/561,811 which is not enabling for a method of treating an autoimmune disorder by administering an antibody that binds to IL-22. Therefore, the claimed subject matter has a priority date of February 23, 2001.

Claim 10 is drawn to a method of treating an autoimmune disorder by administering an antibody that binds to IL-22. Claims 12-14, 16-20, and 40-42 encompass methods of ameliorating symptoms associated with arthritis, more specifically rheumatoid arthritis. Dumoutier *et al.* teach that IL-22 (also known as IL-TIF) is a pro-inflammatory molecule in that it up-regulates acute phase proteins, which may lead to chronic inflammation. It is known in the art that autoimmune diseases such as rheumatoid arthritis are characterized by inflammation and overexpression of pro-inflammatory molecules (see, for example van den Berg (1998) *Springer Semin. Immunopathol.* 20: 149-164). Dumoutier *et al.* also teach that IL-22 exhibits significant amino acid identity with IL-10 (p. 10144). In addition, Dumoutier *et al.* teach that IL-22 and IL-10 bind to receptors that share the subunit IL-10Rβ (p. 10148, column 2). The '799 patent teaches monoclonal anti-IL-22 antibodies, polyclonal anti-IL-22 antibodies, single chain anti-IL-22 antibodies, fragments of anti-IL-22 antibodies, and humanized anti-IL-22 antibodies (column 13, lines 55-60, column 59 through column 66). The '799 patent further teaches the use of anti-IL-22 antibodies in pharmaceutical compositions (column 65, lines 46-50). The IL-22 protein as taught in the '799 patent (SEQ ID NO: 2) is 100% identical to the IL-22 protein of the current application (SEQ ID NO: 2). However, Dumoutier *et al.* and the '799 patent do not teach a method of treating an autoimmune disorder by administering anti-IL-22 antibodies.

Llorente *et al.* teach a method of treating systemic lupus erythematosus (SLE), an autoimmune disorder, by administering anti-IL-10 antibodies (p. 1793, column 1). Llorente *et al.* further teach that patients suffering from SLE and arthritis exhibited a disappearance of arthritis after treatment with anti-IL-10 antibodies (p. 1793, column 2). In addition, Llorente *et al.* teach that IL-10 may stimulate the expression of cytokines, chemokines, selectins, and integrins, and that IL-10 is a pro-inflammatory molecule (p. 1798, column 1).

It would have been obvious to one of ordinary skill in the art to modify the method as taught by Llorente *et al.* by using anti-IL-22 antibodies instead of IL-10 antibodies to treat rheumatoid arthritis. Motivation to modify the method as taught by Llorente *et al.* is provided by Dumoutier *et al.* in that IL-22 is a pro-inflammatory molecule, as is IL-10, and rheumatoid arthritis is characterized by inflammation. Because IL-22 is a pro-inflammatory molecule, and antibodies against pro-inflammatory molecules were successful in treating autoimmune diseases and arthritis associated with autoimmune diseases, one of ordinary skill in the art would have expected the modified method to work as well as the one exemplified.

Conclusion

NO CLAIMS ARE ALLOWED.

The following articles, patents, and published patent applications were found by the Examiner during the art search while not relied upon are considered pertinent to the instant application:

U.S. Patent No. 5,837,232

U.S. Patent Publication No. 2003/0170823

U.S. Patent No. 5,863,796

U.S. Patent No. 5,674,487

U.S. Patent Publication No. 2001/0006637

U.S. Patent No. 6,225,117

Simon *et al.* (2000), *Rheumatology* 39 (suppl. 1): 36-42

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (703) 305-0634. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm. Please note for your records that on January 20, 2004, the examiner's new telephone number will be (571) 272-0886.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RBK
1/12/04

JANET ANDRES
PATENT EXAMINER